



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,437	01/11/2002	Richard Peregrine Bax	P31167C1	9609
7590 01/09/2004			EXAMINER	
GLAXOSMITHKLINE			COOK, REBECCA	
Corporate Intellectual Property - UW2220			ART UNIT	
P.O. Box 1539			PAPER NUMBER	
King of Prussia, PA 19406-0939			1614	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/043,437

Applicant(s)

BAX ET AL.

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO91/15197 in view of Ruberto et al and Jacobsson et al for the reasons given in Paper No. 3.

WO 91/15197 (page 2, lines 21-29, page 7, example 2) discloses mixture of amoxycillin- clavulanate having a ratio of amoxycillin to clavulanate of 7:1.

Ruberto et al (abstract, lines 1-4, page 169, left column, paragraphs 3 and 4) discloses twice daily dosing of amoxycillin-clavulanic acid in children having urinary tract infection at a dosage of 40 mg/kg/day and 20 mg/kg/day of amoxycillin.

Jacobsson et al (abstract, lines 1-5, page 320, left column, fourth full paragraph) discloses twice daily dosing of amoxycillin-clavulanic acid using a mixture having a 4:1 ratio to children having otitis media at a dosage of 26.6 mg/kg.

The instant claims differ over the references in reciting a mixture of amoxycillin-clavulanate having a dosage amount of $45 \pm 10\%$ mg/kg and $6.4 \pm 10\%$ mg/kg of clavulanate. However, allowing for the \pm in the instant ratio, it can change to 5.9.

Art Unit: 1614

In the absence of a showing of unexpected results, no unobviousness is seen in instantly recited ratio. One would be motivated to use the instantly recited ratio of 7:1 over 4:1 of Jacobsson because it is desirable to use as little medication as possible.

Applicants' argument that WO 91/15197 does not address pediatric dosage amounts is not persuasive. WO 91/15197 discloses a liquid preparation, and it is well-known in the art that a liquid preparations is preferable over a tablet for pediatric use. Furthermore, it discloses that a unit dose may contain 125 mg, which would be a pediatric dose.

Applicants' argument that Ruberto teaches away from the twice daily dosage of the present method is not persuasive, since the prescriber would be motivated to use twice daily dosing for convenience and would only consider changing to thrice daily dosing if the patient developed side effects.

Applicants' argument that Jacobsson discloses a higher rate of adverse events in the b.i.d. group compared with the t.i.d. group is not persuasive, since the prescriber would be motivated to use twice daily dosing for convenience and would only consider changing to thrice daily dosing if the patient developed side effects.

The following references are considered cumulative and are no longer applied: 4,537,887 (Rooke et al), GB 2,005,538, Aguedas et al, Feldman et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

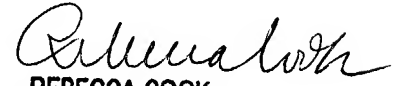
Art Unit: 1614

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


REBECCA COOK
PRIMARY EXAMINER
GROUP 1200 1614

January 7, 2004